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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,923	08/29/2005	Alicia Santos Savio	976-24 PCT/US	5270

23869 7590 03/26/2008  
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EXAMINER
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HISSONG, BRUCE D

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,923	<b>Applicant(s)</b> SAVIO ET AL.	
	<b>Examiner</b> Bruce D. Hissong, Ph.D.	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

2. In the response received on 10/31/2007, Applicants cancelled claims 14-17 and 20. Accordingly, all previous rejections of these claims are moot.

3. Claims 22 and 23 are currently pending and are the subject of this office action.

### Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 23 are rejected under 35 USC § 112, first paragraph, regarding lack of enablement for a method of generating a neutralizing antibody response against autologous IL-15 to a human in need thereof, as originally applied to cancelled claims 16-17 and 20, as set forth on pages 3-4 of the prior office action mailed on 10/18/2007.

Claims 16-17 and 20 were rejected for lack of enablement for methods of treating IL-15 expression-related diseases. In the response received on 10/31/2007, the Applicants argue that the enablement rejection of claims 16-17 and 20 is moot in view of the cancellation of these claims. This argument has been fully considered and is not persuasive.

Claims 22-23 of the instant invention have been amended to include the limitation that the claimed method is for generating a neutralizing antibody response against autologous IL-15 "to a human in need thereof". The instant specification discloses diseases which may benefit from neutralization of

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IL-15, including autoimmune diseases such as rheumatoid arthritis, Crohn's disease, and psoriasis, as well as leukemia, but provides no examples showing that these diseases can actually be treated by the claimed method. As set forth on pages 3-4 of the office action mailed on 10/18/2007, the art teaches unpredictability regarding the role of IL-15 in various diseases. Specifically, the Al-Mughales *et al*, Obermeier *et al*, and Kukita *et al* references suggest that a person of ordinary skill in the art would not predict that neutralization of IL-15 would be effective in treating diseases such as rheumatoid arthritis, inflammatory bowel disease, and adult T-cell leukemia. Therefore, a person of ordinary skill in the art would not be able to predict which human patients are "in need" of IL-15 neutralization, and also would not predict that such neutralization would be effective in treating all possible diseases. For these reasons, a person of ordinary skill in the art would not be able to practice the claimed invention of generating a neutralizing antibody response to autologous IL-15 to all possible patients "in need thereof", and would require further, undue experimentation in order to practice the claimed method in a manner commensurate in scope with the full breadth of the claims.

**Claim Rejections - 35 USC § 112, first paragraph – written description**

Rejection of claim 23 under 35 USC § 112, first paragraph, for incorporation of new matter regarding the limitation of "native IL-15", as set forth on page 5 of the prior office action mailed on 10/18/2007, is withdrawn in response to Applicants' cancellation of claim 14, and amendments to claim 23 to depend from claim 22, which does not recite the limitation of "native IL-15".

**Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claim 23 under 35 USC § 112, second paragraph, as being indefinite regarding the limitation "native IL-15", as set forth on page 5 of the prior office action mailed on 10/18/2007, is withdrawn in response to Applicants' cancellation of claim 14 and amendments to claim 23 to depend from claim 22, which does not recite the limitation of "native IL-15".

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**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 22-23 under 35 USC § 103(a) as being obvious in view of the combination of Grabstein *et al*, Gonzalez *et al*, and Brewer *et al*, as set forth on pages 7-9 of the office action mailed on 10/18/2007, is withdrawn in response to Applicants' amendments to the claims to recite a method for generating a neutralizing antibody response against autologous IL-15 "to a human patient in need thereof". In the response received on 10/31/2007, the Applicants argue that Grabstein *et al* teaches administration of IL-15 to promote the biological activity of IL-15 as a cytokine (e.g. to promote T cell proliferation), but does not teach or suggest neutralization of IL-15 to any human in need thereof.

These arguments have been fully considered and are persuasive in view of the teachings of Grabstein *et al*, which do not teach or suggest which patients would be in need of IL-15 neutralization.

**Conclusion**

No claim is allowable.

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong

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/Robert Landsman/  
Primary Examiner, Art Unit 1647